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In re Patent No. 7,521,387 :
Xue, et al. : DECISION ON REQUEST FOR
Issue Date: April 21, 2009 : RECONSIDERATION OF
Application No. 10/711,477 : PATENT TERM ADJUSTMENT
Filed: September 21, 2004 :
Attorney Docket No. 19441-0072 :

This is in response to the "APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)," filed June 22, 2009, requesting that the patent term adjustment determination for the above-identified patent be changed from nine hundred twelve (912) days to one thousand two hundred sixty-seven (1,267) days.

The request for reconsideration is granted to the extent that the determination has been reconsidered; however, the request for reconsideration of patent term adjustment is **DISMISSED** with respect to making any change in the patent adjustment determination under 35 U.S.C. § 154(b) of 912 days.

On April 21, 2009, the above-identified application matured into U.S. Patent No. 7,521,387 with a patent term adjustment of 912 days. This request for reconsideration of patent term adjustment (including the required fee) was timely filed within two months of the issue date of the patent. See 1.705(d).

Patentees request recalculation of the patent term adjustment based on the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138, 88 U.S.P.Q. 2d 1538 (D.D.C. 2008). Patentees maintain that a portion of the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), 314 of the 578 days, and the period of adjustment due to examination delay, pursuant to 37 CFR § 1.702(a), of 953 days do not overlap as these periods do not occur on the same day.

Patentees argue that the period of adjustment due to the Three Year Delay by the Office, pursuant to 37 CFR § 1.703(b), is 578 days. This 578 day period is calculated based on the application having been filed under 35 U.S.C. §111 on September 21, 2004, and the patent having not issued until April 21, 2009, 2009, three years and 578 days later. Patentees assert that in addition to this 578 day period, they are entitled to a period of adjustment due to examination delay, pursuant to 37 CFR §1.702(a) totalling 953 days.

This 953 day period is the sum of:

- a period of delay of 933 days for the failure by the Office to mail at least one of a notification under 35 U.S.C. 132 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a), pursuant to § 1.702(a)(1); and
- a period of delay of 20 days for the failure by the Office to respond to an amendment filed under 37 CFR 1.312, the filing of said amendment being necessitated by an obvious error introduced by and examiner's amendment.

Patentees are informed that the request for an additional adjustment of 20 days is not supported by the rules pertaining to patent term adjustment and is dismissed.

The period of reduction of 21 days for applicant delay is in dispute. Patentees assert that the February 6, 2009 amendment under 37 CFR 1.312 was filed to correct an obvious error introduced by the examiner's amendment, mailed January 9, 2009. As such, patentees argue that a 20 day adjustment, not a 21 day reduction, should be charged to the USPTO.

37 CFR § 1.704(c)(10) provides that:

Submission of an amendment under § 1.312 or other paper after a notice of allowance has been given or mailed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the lesser of:

- (i) The number of days, if any, beginning on the date the amendment under § 1.312 or other paper was filed and ending on the mailing date of the Office action or notice in

response to the amendment under § 1.312 or such other paper;

or

(ii) Four months;

As stated, in pertinent part, in MPEP 2732:

37 CFR 1.704(c)(10) establishes submission of an amendment under 37 CFR 1.312 or other paper after a notice of allowance has been given or mailed as a circumstance that constitutes a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application. The submission of amendments (or other papers) after an application is allowed may cause substantial interference with the patent issue process.

Certain papers filed after allowance are not considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application. See *Clarification of 37 CFR 1.704(c)(10) - Reduction of Patent Term Adjustment for Certain Types of Papers Filed After a Notice of Allowance has been Mailed*, 1247 Off. Gaz. Pat. Office 111 (June 26, 2001). The submission of the following papers after a "Notice of Allowance" is not considered a failure to engage in reasonable efforts to conclude processing or examination of an application: (1) Fee(s) Transmittal (PTOL-85B); (2) Power of Attorney; (3) Power to Inspect; (4) Change of Address; (5) Change of Status (small/not small entity status); (6) a response to the examiner's reasons for allowance or a request to correct an error or omission in the "Notice of Allowance" or "Notice of Allowability;" and (7) letters related to government interests (e.g., those between NASA and the Office). Papers that will be considered a failure to engage in reasonable efforts to conclude processing or examination of an application include: (1) a request for a refund; (2) a status letter; (3) amendments under 37 CFR 1.312; (4) late priority claims; (5) a certified copy of a priority document; (6) drawings; (7) letters related to biologic deposits; and (8) oaths or declarations.

The filing of an amendment under 37 CFR 1.312 is explicitly listed as a paper that will be considered a failure to engage in reasonable efforts to conclude examination. Accordingly, the period of reduction of 21 days commenced February 6, 2009, the date the amendment was filed, and ended February 26, 2009, the date a response thereto was mailed.

Patentees assert that the total period of Office delay is the sum of the period of Three Years Delay (578 days) and the period of Examination Delay (953 days, per patentees' calculation) to the extent that these periods of delay are not overlapping. Patentees contend that 264 days overlap

Thus, patentees assert entitlement to an overall patent term adjustment of 1,267 days ($933 + 314 + 20$). Patentees alternatively assert entitlement to an overall patent term adjustment of 1,227 ($933 + 314 - 20$)

The Office asserts that the patent issued 3 years and 578 days after its filing date. The Office agrees that the action detailed above was not taken within the specified time frame, and thus, the entry of period of adjustment of 933 days is correct. At issue is whether patentees should accrue an additional 578 days of patent term adjustment for the Office taking in excess of three years to issue the patent, as well as, 933 days for Office failure to take a certain action within a specified time frame (or examination delay). The Office asserts that the overall adjustment is properly reduced 21 days for applicants' failure to engage in reasonable efforts to conclude processing pursuant to 37 CFR 1.704(c)(10).

Under 37 CFR § 1.703(f), patentees are entitled to a period of patent term adjustment equal to the period of delays based on the grounds set forth in 37 CFR §1.702 reduced by the period of time equal to the period of time during which applicants failed to engage in reasonable efforts to conclude prosecution pursuant to 37 CFR §1.704. In other words, the period of Office delay reduced by the period of applicant delay.

The Office contends that all 578 days overlap with the 933 period of Three Year Delay. Patentees' interpretation of the period of overlap has been considered and found to be incorrect. Patentees' calculation of the period of overlap is inconsistent with the Office's interpretation of this provision. 35 U.S.C. 154(b)(2)(A) limits the adjustment of patent term, as follows:

To the extent that the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

Likewise, 37 CFR 1.703(f) provides that:

To the extent that periods of delay attributable to the grounds specified in §1.702 overlap, the period of adjustment granted under this section shall not exceed the actual number of days the issuance of the patent was delayed.

As explained in *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, 69 Fed. Reg. 34283 (June 21, 2004), the Office interprets 35 U.S.C. 154(b)(2)(A) as permitting either patent term adjustment under 35 U.S.C. 154(b)(1)(A)(i)-(iv), or patent term adjustment under 35 U.S.C. 154(b)(1)(B), but not as permitting patent term adjustment under both 35 U.S.C. 154(b)(1)(A)(i)-(iv) and 154(b)(1)(B). Accordingly, the Office implements the overlap provision as follows:

If an application is entitled to an adjustment under 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the period of delay under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay overlap under 35 U.S.C. 154(b)(2)(A). Thus, any days of delay for Office issuance of the patent more than 3 years after the filing date of the application, which overlap with the days of patent term adjustment accorded prior to the issuance of the patent will not result in any additional patent term adjustment. See 35 U.S.C. 154(b)(1)(B), 35 U.S.C. 154(b)(2)(A), and 37 CFR § 1.703(f). See *Changes to Implement Patent Term Adjustment Under Twenty Year Term; Final Rule*, 65 Fed. Reg. 56366 (Sept. 18, 2000). See also *Revision of Patent Term Extension and Patent Term Adjustment Provisions; Final Rule*, 69 Fed. Reg. 21704 (April 22, 2004), 1282 Off. Gaz. Pat. Office 100 (May 18, 2004). See also *Explanation of 37*

CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283 (June 21, 2004).

The current wording of § 1.703(f) was revised in response to the misinterpretation of this provision by a number of applicants. The rule was slightly revised to more closely track the corresponding language of 35 U.S.C. 154(b)(2)(A). The relevant portion differs only to the extent that the statute refers back to provisions of the statute whereas the rule refers back to sections of the rule. This was not a substantive change to the rule nor did it reflect a change of the Office's interpretation of 35 U.S.C. 154(b)(2)(A). As stated in the *Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A)*, the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

This interpretation is consistent with the statute. Taken together the statute and rule provide that to the extent that periods of delay attributable to grounds specified in 35 U.S.C. 154(b)(1) and in corresponding §1.702 overlap, the period of adjustment granted shall not exceed the actual number of days the issuance of the patent was delayed. The grounds specified in these sections cover the A) guarantee of prompt Patent and Trademark Office responses, B) guarantee of no more than 3 year application pendency, and C) guarantee or adjustments for delays due to interference, secrecy orders and appeals. A section by section analysis of 35 U.S.C. 154(b)(2)(A) specifically provides that:

Section 4402 imposes limitations on restoration of term. In general, pursuant to [35 U.S.C.] 154(b)(2)(A)-(C), total adjustments granted for restorations under [35 U.S.C. 154](b)(1) are reduced as follows: (1) To the extent that there are multiple grounds for extending the term of a patent that may exist simultaneously (e.g., delay due to a secrecy order under [35 U.S.C.] 181 and administrative

delay under [35 U.S.C.] 154(b)(1)(A)), the term should not be extended for each ground of delay but only for the actual number of days that the issuance of a patent was delayed; See 145 Cong. Rec. S14,718¹

As such, the period for over 3 year pendency does not overlap only to the extent that the actual dates in the period beginning three years after the date on which the application was filed overlap with the actual dates in the periods for failure of the Office to take action within specified time frames. In other words, consideration of the overlap does not begin three years after the filing date of the application.

In this instance, the relevant period under 35 U.S.C. 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A) is the entire period during which the application was pending before the Office, September 21, 2004 to April 21, 2009. (There were no periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)). 933 days of patent term adjustment were accorded prior to the issuance of the patent for the Office failing to respond within a specified time frame during the pendency of the application. During that time, the issuance of the patent was delayed by 933 days, not 933 + 578 days. The Office took 14 months and 933 days to issue a first Office action. Otherwise, the Office took all actions set forth in 37 C.F.R. § 1.702(a) within the prescribed timeframes. Nonetheless, given the initial 933 days of Office delay and the time allowed within the timeframes for processing and examination, and applicant delays, the patent issued, three years and 578 days after its filing date.

However, zero days of patent term adjustment was entered for the Office taking in excess of 3 years to issue the patent, since the period of delay of 578 days attributable to the delay in the issuance of the patent completely overlaps with the adjustment of 933 days attributable to ground specified in § 1.702(a)(1). Entry of both grounds is neither warranted nor permitted.

In view thereof, no adjustment to the patent term will be made.

¹ The AIPA is title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948), which was incorporated and enacted as law as part of Pub. L. 106-113. The Conference Report for H.R. 3194, 106th Cong. 1st Sess. (1999), which resulted in Pub. L. 106-113, does not contain any discussion (other than the incorporated language) of S. 1948. A section-by-section analysis of S. 1948, however, was printed in the Congressional Record at the request of Senator Lott, See 145 Cong. Rec. S14,708-26 (1999)(daily ed. Nov. 17, 1999).

The Office acknowledges submission of the \$200.00 fee set forth in 37 CFR 1.18(e). No additional fees are required.

Telephone inquiries specific to this matter should be directed to Shirene Willis Brantley, Senior Petitions Attorney, at (571) 272-3230.

A handwritten signature in cursive script, appearing to read 'Alesia M. Brown'.

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